Regulatory Services in South Korea

Regulatory Affairs Services Provider in South Korea

DDReg provides expert-led Regulatory Affairs Services in South Korea to help companies achieve seamless product approvals and lifecycle compliance.

The Ministry of Food and Drug Safety (MFDS) is the central authority overseeing the registration, manufacturing, and distribution of pharmaceutical products and medical devices in South Korea. As part of its mandate, MFDS enforces Good Manufacturing Practices (GMP) to enhance safety control systems. Supporting institutions such as the National Institute of Food and Drug Safety Evaluation (NIFDS), Medical Device Information and Technology Assistance Center (MDITAC), and Pharmaceutical & Medical Device Safety Bureaus work collaboratively under MFDS to manage product registration, monitoring, and compliance.

Pharmaceutical Regulatory Affairs in South Korea

Pharmaceutical products in South Korea are regulated under the Pharmaceutical Affairs Act, which classifies them into drugs and pharmaceutical ingredients. Drug products are further sub-categorized into new drugs, generic drugs, pharmaceuticals requiring data submission. Even if not classified as new, certain drugs must submit safety and efficacy data particularly when changes in dosage form, route of administration, or indications are involved. These submissions are essential for obtaining MFDS product registration and market access.

Our Regulatory Consulting Services In South Korea Portfolio Covers

Why choose DDReg as your South Korea Regulatory Partner?

As your South Korea regulatory affairs consultant , DDReg supports clients across all regulatory phases with custom strategies tailored to local requirements. Our regulatory team ensures that all pharmaceutical regulatory affairs in South Korea align with the most recent MFDS guidelines, helping clients minimize delays and maximize regulatory success.

We work as your extended regulatory team to deliver timely product approvals, accurate documentation and filings, strategic submission planning, expert-level market intelligence.

- MFDS Regulatory Consulting Services
-
- Regulatory Strategies and Expert Views
- Regulatory Due Diligence
- Gap Analysis and Remediation
- New Product Authorizations
- Post Approval Life Cycle Management
- CMC Advisory
- API/DMF
- Regulatory Certification
- eCTD Regulatory Publishing and Submission
- Regulatory Labeling

Country Specific Services

- Regulatory
- Pharmacovigilance
- Labeling
- IPR Support
- Clinical Trial Regulatory
- Medical Devices regulatory services

Our Regulatory Affairs Consulting Services in South Korea portfolio covers:

01 Regulatory Strategies
The pharmaceutical industry operates under stringent regulations to ensure the safety,... efficacy, and quality...
READ MORE →

02 New Product Marketing Authorizations
Navigating marketing authorization is a complex and time-sensitive process. Every...
READ MORE →

03 Gap Analysis and Remediation
In the highly regulated pharmaceutical industry, maintaining compliance is critical...
READ MORE →

04 Regulatory Due Diligence
Regulatory issues arise unexpectedly and can create significant strain on a company's...
READ MORE →

05 API & DMF services
Drug Master Files (DMFs) contain confidential and detailed information regarding API...
READ MORE →

06 CMC Advisory
DDReg's CMC services are dedicated to assisting customers in developing robust and an...
READ MORE →

07 Post Approval Life Cycle Management
Maximize product value with expert pharma lifecycle management. Our dedicated tea...
READ MORE →

08 Certification Services
Partner with DDReg to navigate the complex process of regulatory certification of pharmaceutical...
READ MORE →

09 ANDA and MA Holder Services
Our comprehensive services support both Abbreviated New Drug Applications (ANDA) and...
READ MORE →

© 2025 DDReg Pharma | All Rights Reserved